SENTINEL
DIAGNOSTICS

Urgent Field Safety Notice
N. 02/2019

Product Name	List Number (LN)	Lot Number	Expiration Date
Lithium	8L25-30	n/a	n/a

Date: June 28th, 2019

Details on affected devices:

The purpose of this communication is to inform of an additional SmartWash parameter for the MULTIGENT Lithium reagent, List Number (LN) 8L25-30 to prevent the potential for carryover from the ARCHITECT Lactate Dehydrogenase (LDH) reagent (LN 2P56). Please review the information carefully and follow the mandatory actions.

Description of the problem:

Carryover may be observed between the MULTIGENT Lithium reagent and the ARCHITECT LDH reagent on improperly maintained systems due to the presence of lithium lactate in LDH reagent. As a result, falsely elevated lithium patient results may be generated. To minimize the potential for carryover, an additional SmartWash has been implemented for the MULTIGENT Lithium assay.

Patient Impact:

There is a potential to generate falsely elevated lithium patient results. Therefore, the following actions are mandatory.

Actions to be taken:

- If your laboratory ***does not*** have the LDH reagent installed on your system, no action is required.

- If the LDH reagent is installed on your instrument, please follow the instructions below:

  1. Update the Lithium (LN 8L25-30) assay parameters to add the new SmartWash. For additional information, see the ARCHITECT System Operations Manual, Section 2, *Configure the SmartWash settings (c System)*.

Configure assay parameters — SmartWash

O General | O Calibration | ● SmartWash | O Results | O Interpretation

Assay: **Lith**

COMPONENT	REAGENT/ASSAY	WASH	Volume	Replicates
R1	**LDH00**	**Water**	**345**	**1**
Sample Probe*		**Water**		

*Sample Probe *Sample wash protocol* is **Maximum wash.**

  2. For information on maintaining optimal system performance, refer to your ARCHITECT System Operations Manual.

- Please review the content of this communication with your Medical Director and retain this letter for your laboratory records.

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Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization/individuals where the potentially affected devices have been transferred.

Contact reference person:

If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.

Best regards

JUN 28, 2019

Mario Fangareggi
Head of Marketing

Jun 28, 2019

Patricia Dupé
Head of Quality System